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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) FSTK 1004-1US

	Application Number	Filed
	09/974,781-Conf. #8124	October 10, 2001
	First Named Inventor: Michael G. Kahn et al.	
	Art Unit: 3626	Examiner: D. B. Cobanoglu

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 31,454
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

/Warren S. Wolfeld/
Signature

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Typed or printed name

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Telephone number

September 7, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: September 7, 2007 Electronic Signature for Warren S. Wolfeld: /Warren S. Wolfeld/

E-FILED ON 7 SEPTEMBER 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of inventor(s): Michael G. Kahn et al. Application No. 09/974,781 Confirmation No. 8124 Filing Date: 10 October 2001 Title: Protocol Disambiguation Using a Model-Based Methodology	Group Art Unit: 3626 Examiner: Dilek B. Cobanoglu **CUSTOMER NO. 22470**

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL CONFERENCE REQUEST

Sir:

In response to the Office Action mailed 07 March 2007, Applicants request a pre-appeal brief review because of clear error in the Examiner's rejection.

The independent claims 1, 10 and 42 are rejected under 35 USC 102(3) over Briegs US Patent No. 7,054,823.[1]

The rejection of claims 1 and 42 is clear error because Briegs does not teach the step called for in both claims of "encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object". Briegs certainly does not teach that any of three types of operational uncertainties, specified in both claims, be so encoded.

[1] The Examiner first indicates that only claims 1-3 and 6-22 are rejected, but rejections are set forth for claims 23-51 as well. The claim sets from independent claims 23 and 34 have been canceled without prejudice by an Amendment submitted herewith.

The rejection of claim 10 is clear error because Briegs does not teach a database which includes "a disambiguation comment object which identifies an operational uncertainty in which said protocol specification contains at least one of [the three specified types of] deficiencies."

Applicants have filed this Pre-Appeal Conference Request because this application has already proceeded through three office actions, one advisory action and an extensive telephone interview, and yet again the Examiner has continued to cite references that clearly do not teach the claimed limitations.

I. BRIEF BACKGROUND

The application concerns ways to identify operational problems in a clinical trial protocol for a drug or medical device before the actual trial begins. Operational problems are surprisingly common in clinical trials, and are extremely expensive and complicated to correct after the trial begins.

An "operational" issue is different from a "scientific" issue. A "scientific" issue is an uncertainty about the science related to the drug, such as whether the drug has unwanted side effects. It is precisely why the clinical trial is being conducted. An "operational" issue arises because of inconsistency or ambiguity in the precise specification of trial activities. These problems arise in part because the protocol specification is typically a lengthy text document where the same information is discussed in multiple sections and formats. For example, one section of the protocol specification may specify that a blood test is required while in a different section a table displaying all required activities shows no blood tests at all - this is inconsistent, and it is also ambiguous because the frequency of the blood test has not been specified either.

The subject claims are directed to Applicants' concept that by forcing a protocol specification into a properly designed formal model of a protocol, operational uncertainties embodied in the protocol specification can be discovered before trial execution begins. The formal model is designed such that protocol aspects that do not fit are likely to reveal an operational uncertainty.

It can be seen further that it is the step of encoding, which facilitates the identification of operational uncertainties. It is much harder to identify operational uncertainties simply by studying the protocol specifications in the text document alone. For this reason, many of Applicants' claims call for the step of identifying an operational uncertainty to occur during the

step of encoding a clinical trial protocol. This is not to be confused with encoding *results* of a defined protocol activity into a trial results database while the trial is being executed. Specifically, the encoding step creates an interim protocol specification database which represents the protocol specification text document, but in a structured, machine readable form.

A. Independent Claim 1

Claim 1 takes off from the above general concept and calls for, after an operational uncertainty has been identified by the above methodology:

> encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object. (emphasis added)

Later, but still before execution of the protocol, a graphical-visual representation of the protocol is displayed including a human-perceptible indication that *that particular protocol specification object* has an operational uncertainty associated therewith. The designer then can easily see the problem, and correct it prior to the start of the actual trial.

Thus claim 1 calls for a step of encoding into the database an indication that an operational uncertainty exists. It also calls for the indication to be encoded in association with the protocol specification object with respect to which the operational uncertainty exists.

Moreover, claim 1 calls for the operational uncertainty so encoded, to be one of three specific kinds of deficiencies: (1) "said protocol specification fails to specify a particular parameter for use during protocol execution," or (2) "said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter," or (3) "said protocol specification contains at least two such parameter specifications which are in conflict".

Claim 1 was rejected as being anticipated by Briegs. Briegs describes a system for helping a designer *design* clinical trial protocols. It does not have any mechanism for encoding the fact that an operational uncertainty exists in how the parameters have been described, or for *associating* such encoded facts with a particular protocol specification object. Basically, it appears that Briegs' system attempts to prevent the designer from creating the uncertainty to begin with.

The Examiner cites Briegs, col. 13, lines 21-54 as teaching the above features of Applicants' claim 1. But the cited section of Briegs discusses only the process of encoding the protocol. Nothing in this section says that "*an indication that* [an] operational uncertainty exists" gets encoded into the database. Certainly nothing in this section says that such an indication gets encoded "in association with ... a ... protocol specification object[s] in said database" with respect to which the operational uncertainty exists. And still further, nothing in Briegs teaches or suggests that the operational uncertainty whose existence gets encoded into the database, be one of the three kinds of deficiencies specifically called out in claim 1.

Accordingly, because Briegs fails to teach the step called for in claim 1 of "encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object," and fails further to teach that any such operational uncertainty constitutes one of the three kinds specifically called out in the claim, Briegs fails to anticipate claim 1.

B. Independent Claim 42

Independent claim 42 includes the same limitation set forth above with respect to claim 1, and should be patentable over Briegs for the same reasons.

C. Independent Claim 10

Claim 10 calls roughly for a computer readable medium carrying a protocol specification database. The claim calls for the database to include:

> a disambiguation comment object which identifies an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter, or said protocol specification contains at least two such parameter specifications which are in conflict, said disambiguation comment object being associated with at least a particular one of said objects in said database. (emphasis added)

Again, nothing in Briegs teaches any mechanism for encoding in the database, the *fact* that an operational uncertainty exists. Certainly nothing in Briegs teaches that a "disambiguation comment object" be included in the database to identify such an operational uncertainty.

Nor does anything in Briegs teach that any such disambiguation comment object be associated with any particular protocol specification object in the database.

Nor does anything in Briegs teach that any such operational uncertainty be one of the three kinds of deficiencies specifically called out in the claim.

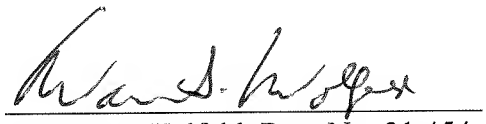
Accordingly, because Briegs fails to teach any of these limitations in claim 10, Briegs fails to anticipate claim 10.

II. CONCLUSION

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0869 (FSTK 1004-1) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: 7 September 2007 By: 

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